

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
GREAT FALLS DIVISION**

ENVIRONMENTAL DEFENSE FUND;
MONTANA ENVIRONMENTAL
INFORMATION CENTER; and CITIZENS
FOR CLEAN ENERGY,

Plaintiffs,

v.

U.S. ENVIRONMENTAL PROTECTION
AGENCY; and ANDREW R. WHEELER, in
his official capacity as Administrator of
the U.S. Environmental Protection
Agency,

Defendants.

Case No. 4:21-cv-00003-BMM-JTJ

The Honorable Brian Morris,
Chief Judge

PLAINTIFFS' STATEMENT OF UNDISPUTED FACTS

1. On April 30, 2018, the EPA published in the Federal Register a notice of proposed rulemaking for a new rule, titled “Strengthening Transparency in Regulatory Science.” *See* 83 Fed. Reg. 18768, 18768 (proposed Apr. 30, 2018). The notice requested public comment on a rule that would “direct the EPA to ensure” that the scientific research “underlying its actions is publicly available in a manner sufficient for independent validation.” *Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information*, 86 Fed. Reg. 469, 473 (Jan. 6, 2021) (describing the proposed rule).

2. The EPA published a supplemental notice of proposed rulemaking on March 18, 2020. *See Strengthening Transparency in Regulatory Science*, 85 Fed. Reg. 15396 (proposed Mar. 18, 2020).

3. The EPA's Science Advisory Board warned that the rule "risks serious and perverse outcomes." Gupta Decl., Ex. B at 27. "[T]here are legitimate legal, ethical, professional and financial reasons," it wrote, "why researchers may be unable or unwilling to fully share 'data'—including statutes protecting participant privacy, experimental protocols assuring confidentiality of data for human subjects, and (for past studies) issues related to degradation and custody of data." *Id.* at 26. The board noted that the EPA and scientific institutions have "recognized that such constraints on availability of data do not prevent studies from being verified in other ways—or preclude those studies from being considered in regulatory decisions." *Id.* It concluded that the agency had provided "minimal justification ... for why existing procedures and norms utilized across the U.S. scientific community, including the federal government, are inadequate," or for how the rule would "improve transparency and the scientific integrity of the regulatory outcomes in an effective and efficient manner." *Id.* at 27.

4. Thomas Sinks, the EPA's Director of the Office of the Science Advisor, wrote a Differing Scientific Opinion opposing the proposed rule. "Human subjects research is the most predictive data for establishing the human health impact from

environmental exposures,” he wrote, and disregarding or diminishing that research means “setting aside relevant science”—leading to “poorly developed rules.” Gupta Decl., Ex. C at 3–4. The result, he concluded, will be to “compromise the scientific integrity of our scientists, the validity of our rulemaking, and possibly the health of the American People.” *Id.* at 4.

5. The EPA received hundreds of thousands of public comments opposing the rule, including comments from plaintiff Environmental Defense Fund.

6. After signing a final rule on December 30, 2020, the EPA announced the rule on January 5, 2021, and published it in the Federal Register the next day.

7. The final rule adds new provisions to the Code of Federal Regulations that limit, for the first time, the weight that the agency is authorized to afford to studies that rely on “dose-response data”—that is, “data used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect.” 86 Fed. Reg. 492 (to be codified at 40 C.F.R. § 30.2). The new provisions provide that the “EPA shall give greater consideration to pivotal science where the underlying dose-response data” are “available in a manner sufficient for independent validation.” *Id.* (to be codified at 40 C.F.R. § 30.5). When the underlying data are not so available, by contrast, the agency “will give them lesser consideration.” *Id.* The rule grants the Administrator limited authority to “grant an exemption” to the requirement, “on a case-by-case

basis,” for one of five specific, enumerated reasons documented in the record. *Id.* at 493 (to be codified at 40 C.F.R. § 30.7).

8. The agency deemed the rule as one that only “governs internal agency procedures for determining the consideration to afford various studies.” *Id.* at 472. Based on its view that the rule is purely procedural, the EPA asserted that its rulemaking was “exempt from the ... delayed effective-date requirements set forth in” section 553(d) of the APA. *Id.* Accordingly, it provided that the “final rule is effective on January 6, 2021”—its date of publication in the Federal Register. *Id.* at 470.

9. Assuming “arguendo,” however, “that the delayed effective-date requirement of the Act applied,” the EPA stated that it “determined that there would be good cause, consistent with 5 U.S.C. 553(d)(3), for making this final rule effective immediately.” *Id.* at 472. The agency claimed that “immediate implementation of the rule, with its goals of ensuring transparency and consistency in how the agency considers dose-response data underlying pivotal science to be used in significant regulatory decisions and influential scientific information, is crucial for ensuring confidence in EPA decision-making.” *Id.*

10. The plaintiffs intend to petition the EPA to administratively postpone the effective date of the Rule under Section 705 of the Administrative Procedure Act

(APA). But, because of the EPA's decision to issue the Rule effective immediately, the plaintiffs are deprived of their ability to seek that stay.

January 11, 2021

Respectfully submitted,

/s/Deepak Gupta

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* *Pro hac vice* applications pending

CERTIFICATE OF SERVICE

I hereby certify that on January 11, 2021, I electronically filed this statement of undisputed facts through this Court's CM/ECF system. I understand that notice of this filing will be sent to all parties by operation of the Court's electronic filing system.

January 11, 2021

/s/ Derf Johnson
Derf Johnson